ADAM A. REEVES (NYBN 2363877)
Attorney for the United States,
Acting Under Authority Conferred By 28 U.S.C. § 515

HALLIE HOFFMAN (CABN 210020)
Chief, Criminal Division

JEFF SCHENK (CABN 234355)
JOHN C. BOSTIC (CABN 264367)
ROBERT S. LEACH (CABN 196191)
Assistant United States Attorneys

150 Almaden Boulevard, Suite 900
San Jose, California 95113
Telephone: (408) 535-5061
Fax: (408) 535-5066
jeffrey.b.schenk@usdoj.gov

Attorneys for United States of America

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for July 17, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government's Statement

A. Current Status Regarding Agency Documents

In advance of the June 28, 2019 hearing on Defendants' Motion to Compel, the prosecution met and conferred with defense counsel regarding certain categories of documents Defendants believed were held by federal government agencies including the FDA, CMS, and the California Department of Public

Health (CDPH). During those discussions, government counsel informed defense counsel that the prosecution did not control the requested documents, but nonetheless offered to make efforts to obtain those documents from the agencies in question and produce them to the defense. Defendants rejected the government's offer and filed a motion to compel. Nevertheless, on May 9, 2019, the government sent letters to representatives of FDA and CMS requesting access to the specific categories of documents identified by Defendants. On June 28, 2019, the Court held a motion hearing where the government informed the Court of the status of those requests and the agencies' positions regarding production of the documents.

Following the hearing on June 28, 2019, the prosecution continued its efforts to obtain the requested materials from FDA and CMS. Government counsel urged the agencies to produce all requested documents as soon as possible and provided them with copies of the Court's June 28, 2019 order and a transcript of the motion hearing. The prosecution's discussions with the agencies focused on potential solutions to the issues preventing a prompt and complete production—in particular, the agencies' need for a protective order and a waiver from the Assignee controlling Theranos's right to trade secrets and confidential corporate information.

Accordingly, government counsel prepared a stipulated protective order designed to address the agencies' concerns regarding sensitive information and facilitate production of agency documents. The resulting proposed protective order (attached hereto as Exhibit A) contains provisions similar to those in the Supplemental Stipulated Protective Order entered in the SEC litigation for the same purpose. (See Dkt. No. 83 in 18-cv-01603 EJD).

Government counsel also contacted counsel for the Theranos Assignee. The Assignee had previously granted a waiver authorizing FDA and CMS to produce trade secrets and other confidential corporate information in response to Balwani's subpoena in the SEC civil case, but Assignee counsel informed the government that Balwani's lawyers had not requested a similar waiver applicable to the criminal case. The government remedied this omission and asked for such a waiver, obtaining the Assignee's agreement after providing the proposed protective order to Assignee counsel.

During the week of July 8, FDA and CMS responded to the Court's order with letters to all parties clarifying and revising their positions on the document requests. FDA's letter is attached hereto

as Exhibit B; CMS's letter is attached as Exhibit C. In those letters, both FDA and CMS confirm their intention to compile and produce documents in their possession responsive to all six of the categories chosen by Defendants. Both FDA and CMS have prepared initial document productions totaling more than 10,000 pages, which can be produced as soon as the protective order is entered and the Assignee's promised waiver is received.

According to their letters, the agencies will then continue to collect and review documents in response to the pending requests, producing all responsive materials other than limited categories of information consisting of attorney-client privileged communications, attorney work product, and third-party trade secrets / confidential information not covered by the Theranos Assignee waiver.[1] FDA has stated that it no longer intends to withhold Theranos-specific documents based on the deliberative process privilege, and CMS has similarly confirmed that it will not withhold documents on that basis.

CMS predicts that it can produce the documents it has already collected and loaded into its review database by mid-August. In the meantime, it is working to collect and load the rest of its potentially responsive documents for review. For its part, FDA estimates that its production of all responsive documents may take as long as six months. Defendants have objected to this schedule, and the prosecution shares the view that such a delay is unacceptable. The prosecution will make every effort to speed up the FDA's production of documents, up to and including serving its own Rule 17 subpoena on the agency if necessary. Today, both FDA and CMS represented to the prosecution that they are exploring options to complete their productions more quickly than the projections in their letters last week.

In sum, the following progress has been made since the June 28, 2019 hearing:

- Government drafted stipulated protective order incorporating input from FDA, CMS, Theranos Assignee, and defense counsel;
- Theranos Assignee agreed to provide a waiver allowing FDA and CMS production of

[1] FDA also states that it will withhold from production materials available from public media or similar organizations (which the government understands to apply to widely distributed news bulletin emails and similar documents) or materials containing "personal and private information" as well as information that could be used to identify a confidential informant. In recent conversations with government counsel, FDA has agreed not to withhold such personal and private information from its production and to rely on the proposed Supplemental Protective Order in producing such information.

Theranos confidential information under protective order;

- FDA and CMS confirmed agreement to search for and produce documents in their possession responsive to all requested categories;
- FDA and CMS prepared substantial initial productions that will be transmitted as soon as protective order is entered and waiver provided;
- FDA and CMS agreed not to withhold responsive documents regarding Theranos based on deliberative process privilege;
- FDA and CMS agreed not to withhold or redact personally identifying information in responsive documents;
- FDA agreed not to withhold responsive documents based on relevance objections; and
- CDPH completed email search confirming no additional responsive documents.

B. Status of Other Issues Addressed at June 28, 2019 Hearing

The Court's June 28, 2019 order states: "No later than July 12, 2019, the Government shall complete its Brady review of the SEC agent notes and memoranda relating to the interviews of Craig Hall and Bryan Tolbert and produce to the Defendants any *Brady* material contained therein." On July 9, 2019, the Government provided a disclosure to the defendants regarding the Hall and Tolbert interviews. The Government will review the remainder of the SEC notes for discoverable information and make any required disclosures to the defense. On July 9, 2019, the Government made available for the defense's review notes of interviews by FBI, USPIS, and FDA-CI criminal investigators.

C. Anticipated Next Steps

As described above, FDA and CMS have agreed to produce documents responsive to all of Defendants' requested categories once a supplemental protective order is entered in this case and the Theranos Assignee provides a waiver allowing production of confidential corporate information. In turn, the Assignee has agreed to give such a waiver upon entry of the same protective order. Accordingly, the government respectfully requests that the Court enter the attached Supplemental Protective Order. The Assignee will then give its waiver and FDA and CMS will transmit their initial document productions. The government has asked the agencies to produce their documents to all parties simultaneously to minimize delay. The agencies will then continue to collect, review, and produce

responsive documents on a rolling basis, with the government assisting in any way it can to ensure that the process is completed as quickly as possible.

The Court's June 28, 2019 order clearly conveyed the Court's view that the responsive documents currently held by FDA and CMS should be produced to the prosecution and the defense as soon as possible. Accordingly, the government believes that an additional Court order is unnecessary at this time. The government intends, however, to monitor the agencies' ongoing document productions—in particular, the agencies' efforts to complete their productions sooner than their initial projections—and will report to the Court immediately if a further order would help resolve this matter.

The Government will continue to make available for the defense's review any additional notes of interview by FBI, USPIS, and FDA-CI generated in the prosecution.

Finally, consistent with the Court's Order, the parties have jointly prepared a proposed pretrial schedule, which is attached hereto as Exhibit D.

II. Defendants' Statement

A. Agency Documents

The Court's inquiry at the June 28, 2019 hearing was clear: will the CMS and FDA ("the agencies") produce documents responsive to the six defense requests and, if so, when? On July 9 and 12, 2019, those agencies responded that they will gather *some but not all* documents responsive to the requests, on an unworkable timeline. Accordingly, a Court order is needed to ensure the defense will receive in a timely manner the documents they are entitled to under *Santiago* and *Bryan*. Only an order from this Court, not voluntary production by the agencies allowing them to collect some documents but not others, will ensure that all responsive documents from the agencies are produced, and safeguard defendants' constitutional rights to a fair trial and to present a complete defense.[2]

Notwithstanding the efforts set forth above, the government has been unable to obtain assurance from the agencies that they will produce *all* documents responsive to the six defense requests. To the

[2] To clarify the government's statement that the meet and confer conference was "in advance of the June 28, 2019 hearing," the actual date of that conference was April 5, 2019. The government did not request documents from the agencies until May 9, 2019, and they still have not complied.

contrary, rather than answer the simple question posed by the Court of whether they will produce the documents and when, the agencies dedicated a collective eight (8) pages (*See* Exhibits B and C) to describing what they have done to date to gather *some* responsive documents while failing to acknowledge that other responsive documents likely fall outside of those efforts.

The government's position during the drafting of this status report highlights that disconnect. The initial draft of the government's section of this report stated that the agencies confirmed that they would search for "*all* non-privileged documents in their possession responsive to any requested categories." (emphasis added) When defense counsel pointed out that the agencies' letters did not provide confirmation that *all* documents would be produced, and asked whether the government had independently obtained that assurance, the government conceded that the agencies had not actually agreed to produce *all* documents, and it revised the sentence to remove the reference to an agreement to produce "all non-privileged documents." *See* Exhibit E (7/15/19 email exchange between L. Wade and J. Bostic).

Moreover, the FDA says it will need up to six months to complete its production. CMS does not even give a timeframe for completing its production once it sets up a review database for some of the documents. Even the government agrees that the FDA's timeline, in particular, is "unacceptable" given the trial date in this case. The government does not even comment on CMS's vague timeline. The government's solution that it may have to resort to issuing a Rule 17 subpoena is, respectfully, unworkable, and likely only to lead to further delay. Moreover, the government's proposed solution is a concession that the agencies may not properly comply on their own without a Court order, and that the government anticipates that it may need help from the Court to achieve full compliance. This is after months of vague and inadequate correspondence from the agencies. The much simpler, direct, and appropriate solution is a Court order under Rule 16.

As a result, a Court order requiring collection and production of the six categories of documents, as well as specific deadlines for those productions, is necessary to ensure full and prompt compliance with the government's Rule 16 obligations. The government should not be allowed to satisfy its obligations by permitting the agencies to choose the custodians and categories of documents they prefer to collect and produce, and select the timeframes for production.[3]

B. SEC Notes.

By letter dated July 9, 2019, AUSA Robert Leach informed the defense of the contents of SEC notes regarding investor witness Craig Hall, pursuant to the government's *Brady* obligations. The defense is reviewing this material and will assess whether it believes further action is needed with respect to the SEC notes.

C. Agent Notes.

While the government has permitted the defense to access agent notes from witness interviews by reviewing them at the U.S. Attorney's Office, the government has refused to provide the defense with hard copies of these notes. On July 10, 2019, Mr. Balwani and his counsel conducted an in-person review of a subset of handwritten notes from the prosecution's witness interviews, and two days later, Mr. Balwani renewed his request that the government provide the defense with hard copies of these agent notes. *See* Exhibit F (7/12/2019 Letter from S. Cazares). Three attorneys from Mr. Balwani's defense team, and Mr. Balwani, spent almost 6 hours reviewing agent notes on July 10, but got through only a handful of them in that time due to the dense nature of the notes, very difficult and at times cryptic handwriting, and the need to constantly refer to the 302s to look for material discrepancies.

Nevertheless, even that session unearthed considerable undisclosed *Brady* material, including material variances between the contemporaneous, handwritten agent notes, and the resulting typewritten memoranda previously disclosed to the defense. As a result of the system the government is trying to set up here, Mr. Balwani has been put in the catch-22 position of having to reveal the defense's work

[3] Regarding the government's claim about the circumstances of contacting the Assignee for a protective order, Mr. Balwani does not agree with the accuracy of the government's characterization. However, Mr. Balwani is pleased that the agencies will no longer be able to claim this issue as a barrier to document production.

product and trial strategy to the government in order to obtain copies of agent notes, which is the only meaningful way he would be able to use this *Brady* material for trial preparation and at trial. If the defense identifies any *Brady* material in the notes, which it already has, the defense must get copies of all the notes to avoid having to reveal defense strategy and work product to the government by telling the government its selection of particular notes. The system set up by the government where the defense has to tell them which notes it thinks contain exculpatory evidence is thus unworkable and an improper intrusion into defense strategies and work product. There is no countervailing government interest that could possibly justify the government's continued refusal to provide copies of the agent notes to counsel and instead require the defense to continue to travel to review agent notes in-person at the U.S. Attorney's Office. *See* Exhibit F (7/12/2019 Letter from S. Cazares).

DATED: July 15, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/
JEFF SCHENK
JOHN C. BOSTIC
ROBERT S. LEACH
Assistant United States Attorneys

DATED: July 15, 2019

/s/
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

DATED: July 15, 2019

/s/
JEFFREY B. COOPERSMITH
STEVE CAZARES
Attorneys for Ramesh "Sunny" Balwani